

EOTA – *Quality Manual*



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Quality Manual

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A	Initial Release
B	Section V – added justification for exclusion “...because EOTA does not require the use of monitoring and measurement devices in the conduct of business.”
07_1205	Added MGTP-004, Employee Satisfaction to Quality Manual
08_0818	Changed P-008 from Corrective Action and Preventive Action to read Corrective/Preventive Action & Improvement Opportunity
09_0625	Crosswalk from ISO 9001:2000 to ISO 9001:2008 and addition of MGTP-005, EOTA Inventory Identification Process.
10_0827	Updated Quality Manual to reflect additional processes.
10_0928	Updated Quality Manual to reflect changes with TPP implementation.
11_0329	Updated Quality Manual to reflect process name changes and deleted references to obsolete form ITTP-013, Desktop Support.

I. Purpose

The purpose of this Manual is to define the scope of the Emergency Management Training Academy (EOTA) Business Management System (BMS) and demonstrate compliance to the ISO 9001:2008 Standard. This Manual makes reference to the applicable EOTA processes.

II. Scope

This document applies to EOTA Employees.

III. Responsibility

Responsibilities related to the EOTA BMS are defined in applicable processes and related documents.

IV. Definitions

ISO 9000:2008 Quality Management System – Fundamentals and Vocabulary

ISO 9001:2008 Quality Management System – Requirements

ISO 9004:2008 Quality Management System – Guidelines for Performance Improvement

V. Scope of Registration

The EOTA designs and develops state-of-the-art training and education products, and conducts exercise, computer-based, and classroom training for the Department of Energy/National Nuclear Security Administration. The Emergency Operations Training Academy is recognized as the model technical training provider for DOE emergency operations personnel, and is dedicated to our role in the enhancement of the readiness of personnel in the emergency operations community.

Area 7.6 of the ISO 9001:2008 Standard is excluded, because EOTA does not require the use of monitoring and measurement devices in the conduct of business.

Quality Policy:

The EOTA aspires toward continual improvement in achieving excellence by providing state-of-the-art training opportunities for emergency operations customers to enhance readiness response capabilities.

To ensure effectiveness in business practices, the EOTA is committed to:

- Provide cost effective training to meet customer needs and ensure satisfaction and continual improvement

- Demonstrate adherence to quality business practices

- Provide employees with a healthy, secure working environment

4.0 Quality Management System

4.1 General Requirements

The Organization **shall** establish, document, implement and maintain a quality management system and continually improve the effectiveness in accordance with the requirements of this International Standard.

The Organization **shall**:

Area	Requirement	Response
4.1a	Determine the processes needed for the quality management system and their application throughout the Organization (see 1.2),	Q-001, Quality Manual
4.1b	Determine the sequence and interaction of these processes,	Q-001, Quality Manual Q-003, Sequence and Interaction - Continual Improvement
4.1c	Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,	P-001, Document Control P-002, Control of External Documents P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-007, Internal Audit P-008, Corrective/Preventive Action
4.1d	Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,	Q-001, Quality Manual MGTP-002, Skill Set Training Process P-004, Business System Management Review P-007, Internal Audit
4.1e	Monitor, measure where applicable, and analyze these processes, and	P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-007, Internal Audit
4.1f	Implement actions necessary to achieve planned results and continual improvement of these processes.	P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-007, Internal Audit P-008, Corrective/Preventive Action P-012, Process/Continual Improvement
	These processes shall be managed by the Organization in accordance with the requirements of this International Standard.	P-004, Business System Management Review Q-001, Quality Manual

Area	Requirement	Response
	<p>Where an Organization chooses to outsource any process that affects product conformity to requirements, the Organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.</p>	<p>ADMP-001, Procurement Process ADMP-003, Receiving Inspection Process</p>
	<p>Note 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.</p>	<p>ISDP-002, Training Production Process ITTP-014, Network Technical Support P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-011, Nonconforming Material/Product Process ADMP-001, Procurement Process</p>
	<p>Note 2: An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.</p>	
	<p>Note 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as</p> <ul style="list-style-type: none"> a) the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements, b) the degree to which the control for the process is shared, c) the capability of achieving the necessary control through the application of 7.4. 	

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation **shall** include:

Area	Requirement	Response
4.2.1a	Documented statements of a quality policy and quality objectives,	P-004, Business System Management Review Q-001, Quality Manual Q-002, Quality Policy
4.2.1b	A quality manual,	Q-001, Quality Manual
4.2.1c	Documented procedures and records required by this International Standard, and	P-001, Document Control P-003, Control of Records P-007, Internal Audit P-008, Corrective/Preventive Action P-011, Nonconforming Material/Product Process P-012, Process/Continual Improvement
4.2.1d	Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.	P-001, Document Control Process P-004, Business System Management Review P-007, Internal Audit P-008, Corrective/Preventive Action
	Note: Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.	

4.2.2 Quality Manual

The Organization **shall** establish and maintain a quality manual that includes:

Area	Requirement	Response
4.2.2a	The scope of the quality management system, including details of and justification for any exclusions (see 1.2),	Q-001, Quality Manual – Sections V
4.2.2b	The documented procedures established for the quality management system, or reference to them, and	Q-001, Quality Manual
4.2.2c	A description of the interaction between the processes of the quality management system.	Q-001, Quality Manual Q-003, EOTA Processes: Sequence and Interaction - Continual Improvement

4.2.3 Control of Documents

Area	Requirement	Response
	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.	P-001, Document Control P-003, Control of Records

A documented procedure **shall** be established to define the controls needed:

Area	Requirement	Response
4.2.3a	To approve documents for adequacy prior to issue,	P-001, Document Control
4.2.3b	To review and update as necessary and re-approve documents,	P-001, Document Control
4.2.3c	To ensure that changes and the current revision status of documents are identified,	P-001, Document Control
4.2.3d	To ensure that relevant versions of applicable documents are available at points of use,	P-001, Document Control
4.2.3e	To ensure that documents remain legible and readily identifiable,	P-001, Document Control
4.2.3f	To ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and	P-002, Control of External Documents
4.2.3g	To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.	P-001, Document Control P-002, Control of External Documents

4.2.4 Control of Records

Area	Requirement	Response
	Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.	P-003, Control of Records

5.0 Management Responsibility

5.1 Management Commitment

Top management **shall** provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

Area	Requirement	Response
5.1a	Communicating to the Organization the importance of meeting customer as well as statutory and regulatory requirements,	P-004, Business System Management Review P-005, Student Feedback Process P-009, Internal Communication
5.1b	Establishing the quality policy,	P-004, Business System Management Review Q-002, Quality Policy
5.1c	Ensuring that quality objectives are established,	P-004, Business System Management Review
5.1d	Conducting management reviews, and	P-004, Business System Management Review
5.1e	Ensuring the availability of resources.	P-004, Business System Management Review

5.2 Customer Focus

Area	Requirement	Response
	Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).	ISDP-002, Training Production Process ITTP-011, Student Support P-004, Business System Management Review P-005, Student Feedback Process

5.3 Quality Policy

Top management **shall** ensure that the quality policy:

Area	Requirement	Response
5.3a	Is appropriate to the purpose of the Organization,	P-004, Business System Management Review Q-002, Quality Policy
5.3b	Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,	P-004, Business System Management Review P-006, Measurement, Analysis, and Improvement Q-002, Quality Policy
5.3c	Provides a framework for establishing and reviewing quality objectives,	P-004, Business System Management Review (Metric Summary)
5.3d	Is communicated and understood within the Organization, and	P-004, Business System Management Review P-009, Internal Communication Q-002, Quality Policy
5.3e	Is reviewed for continuing suitability.	P-004, Business System Management Review Q-002, Quality Policy

5.4 Planning

5.4.1 Quality Objectives

Area	Requirement	Response
	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1a)], are established at relevant functions and levels within the Organization. The quality objectives shall be measurable and consistent with the quality policy.	P-004, Business System Management Review, Metric Summary P-009, Internal Communication ISDP-002, Training Production Process

5.4.2 Quality Management System Planning

Top management **shall** ensure that:

Area	Requirement	Response
5.4.2a	The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and	P-004, Business System Management Review P-009, Internal Communication
5.4.2b	The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	P-004, Business System Management Review P-007, Internal Audit

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Area	Requirement	Response
5.5.1	Top management shall ensure that responsibilities and authorities are defined and communicated within the Organization.	MGTP-002, Skill Set/Training Process Management Representative Appointment Letter MGTF-008, EOTA Organizational Chart P-009, Internal Communication

5.5.2 Management Representative

Area	Requirement	Response
5.5.2	Top management shall appoint a member of the Organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes:	Management Representative Appointment Letter

Area	Requirement	Response
5.5.2a	Ensuring that processes needed for the quality management system are established, implemented and maintained,	P-004, Business System Management Review P-007, Internal Audit
5.5.2b	Reporting to top management on the performance of the quality management system and any need for improvement, and	P-004, Business System Management Review
5.5.2c	Ensuring the promotion of awareness of customer requirements throughout the Organization.	P-004, Business System Management Review P-009, Internal Communication

5.5.3 Internal Communication

Area	Requirement	Response
5.5.3	Top management shall ensure that appropriate communication processes are established within the Organization and that communication takes place regarding the effectiveness of the quality management system.	P-004, Business System Management Review P-009, Internal Communication

5.6 Management Review

5.6.1 General

Area	Requirement	Response
	Top management shall review the Organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.	P-004, Business System Management Review
	Records from management reviews shall be maintained (see 4.2.4).	P-004, Business System Management Review P-003, Control of Records

5.6.2 Review Input

The input to management review **shall** include information on:

Area	Requirement	Response
5.6.2a	Results of audits,	P-004, Business System Management Review P-010, Process Deviation P-011, Nonconforming Material/Product Process
5.6.2b	Customer feedback,	P-004, Business System Management Review P-005, Student Feedback Process P-006, Measurement, Analysis, and Improvement QAMP-002, Course Maintenance Process
5.6.2c	Process performance and product conformity,	P-004, Business System Management Review

Area	Requirement	Response
		P-006, Measurement, Analysis and Improvement QAMP-002, Course Maintenance Process P-007, Internal Audit
5.6.2d	Status of preventive and corrective actions,	P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-008, Corrective/Preventive Action P-012, Process/Continual Improvement
5.6.2e	Follow-up actions from previous management reviews,	P-004, Business System Management Review
5.6.2f	Changes that could affect the quality management system, and	P-004, Business System Management Review
5.6.2g	Recommendations for improvement.	P-004, Business System Management Review

5.6.3 Review Output

The output from the management review **shall** include any decisions and actions related to:

Area	Requirement	Response
5.6.3a	Improvement of the effectiveness of the quality management system and its processes,	P-004, Business System Management Review
5.6.3b	Improvement of product related to customer requirements, and	P-004, Business System Management Review
5.6.3c	Resource needs.	P-004, Business System Management Review

6.0 Resource Management

6.1 Provision of Resources

The Organization **shall** determine and provide the resources needed:

Area	Requirement	Response
6.1a	To implement and maintain the quality management system and continually improve its effectiveness, and	Management Representative Appointment Letter ITTP-014, Network Technical Support P-004, Business System Management Review P-010, Process Deviation P-011, Nonconforming Material/Product Process P-008, Corrective/Preventive Action P-009, Internal Communication P-012, Process/Continual Improvement
6.1b	To enhance customer satisfaction by meeting customer requirements.	ITTP-014, Network Technical Support P-004, Business System Management Review P-005, Student Feedback Process P-006, Measurement, Analysis, and Improvement

6.2 Human Resources

6.2.1 General

Area	Requirement	Response
6.2.1	Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.	MGTP-002, Skill Set Training Process
	Note: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.	

6.2.2 Competence, Training and Awareness

The Organization **shall**:

Area	Requirement	Response
6.2.2a	Determine the necessary competence for personnel performing work affecting conformity to product requirements,	MGTP-002, Skill Set Training Process
6.2.2b	Where applicable, provide training or take other actions to achieve the necessary competence,	MGTP-002, Skill Set Training Process P-009, Internal Communication
6.2.2c	Evaluate the effectiveness of the actions taken,	MGTP-002, Skill Set Training Process
6.2.2d	Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and	MGTP-002, Skill Set Training Process P-004, Business System Management Review
6.2.2e	Maintain appropriate records of education, training, skills and experience (see 4.2.4).	MGTP-002, Skill Set Training Process P-003, Control of Records

6.3 Infrastructure

The Organization **shall** determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

Area	Requirement	Response
6.3a	Buildings, workspace and associated utilities,	P-004, Business System Management Review
6.3b	Process equipment (both hardware and software), and	ITTP-014, Network Technical Support P-004, Business System Management Review ADMP-001, Procurement Process
6.3c	Supporting services (such as transport, communication or information systems).	ADMP-002, Vendor Selection and Management ADMP-004, Contractor Travel Process ITTP-014, Network Technical Support P-004, Business System Management Review ADMP-001, Procurement Process

6.4 Work Environment

Area	Requirement	Response
	The Organization shall determine and manage the work environment needed to achieve conformity to product requirements.	P-004, Business System Management Review
	Note: The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).	

7.0 Product Realization

7.1 Planning of Product Realization

Area	Requirement	Response
	The Organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the Quality Management System (see 4.1).	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ISDP-010, Course/Analysis Initiation Process ISDP-011, Exercise Course Implementation Process ISDP-012, ILT Course Implementation Process ISDP-013, WBT Course Implementation Process ISDP-014, Course Evaluation and Close Out Process ISDP-015, WBT-ILT-EX Course Design Process ISDP-016, ILT Course Development Process ISDP-017, Exercise Development Process ISDP-018, WBT Course Development Process

In planning product realization, the Organization **shall** determine the following, as appropriate:

Area	Requirement	Response
7.1a	Quality objectives and requirements for the product;	ISDP-002, Training Production Process ISDP-010, Course/Analysis Initiation Process ISDP-014, Course Evaluation and Close Out Process
7.1b	The need to establish processes and documents, and to provide resources specific to the product;	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ISDP-011, Exercise Course Implementation Process ISDP-012, ILT Course Implementation Process

Area	Requirement	Response
		ISDP-013, WBT Course Implementation Process ISDP-015, WBT-ILT-EX Course Design Process ISDP-016, ILT Course Development Process ISDP-017, Exercise Development Process ISDP-018, WBT Course Development Process
7.1c	Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;	ISDP-002, Training Production Process ISDP-016, ILT Course Development Process ISDP-017, Exercise Development Process ISDP-018, WBT Course Development Process ISDP-011, Exercise Course Implementation Process ISDP-012, ILT Course Implementation Process ISDP-013, WBT Course Implementation Process ISDP-014, Course Evaluation and Close Out Process
7.1d	Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).	ISDP-002, Training Production Process ISDP-014, Course Evaluation and Close Out Process ISDP-005, Functional-Job-Task Analysis Process ITTP-012, Graphic Design Support P-003, Control of Records

The output of this planning **shall** be in a form suitable for the Organization's method of operations.

7.2 Customer-related Processes

7.2.1 Determination of Requirements Related to the Product

The Organization shall determine:

Area	Requirement	Response
7.2.1a	Requirements specified by the Customer, including the requirements for delivery and post-delivery activities,	ISDP-002, Training Production Process ITTP-012, Graphic Design Support ITTP-015, Website Development-Maintenance P-010, Process Deviation
7.2.1b	Requirements not stated by the Customer but necessary for specified or intended use, where known	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-011, Student Support ITTP-012, Graphic Design Support ITTP-015, Website Development-Maintenance
7.2.1c	Statutory and regulatory requirements applicable to the product, and	ISDP-001, Course Design-Development Process ISDP-002, Training Production Process ITTP-012, Graphic Design Support ITTP-015, Website Development-Maintenance
7.2.1d	Any additional requirements considered necessary by the Organization.	ISDP-002, Training Production Process ITTP-012, Graphic Design Support ITTP-015, Website Development-Maintenance
	Note: Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.	

7.2.2 Review of Requirements Related to the Product

The Organization **shall** review the requirements related to the product. This review **shall** be conducted prior to the Organization's commitment to supply a product to a Customer (e.g., submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and **shall** ensure that:

Area	Requirement	Response
7.2.2a	Product requirements are defined,	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance
7.2.2b	Contract or order requirements differing from those previously expressed are resolved, and	ISDP-002, Training Production Process ITTP-015, Website Development-Maintenance
7.2.2c	The Organization has the ability to meet the defined requirements.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance
	Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance P-003, Control of Records
	Where the customer provides no documented statement of requirement, the Customer requirements shall be confirmed by the Organization before acceptance.	ISDP-002, Training Production Process ITTP-015, Website Development-Maintenance
	Where product requirements are changed, the Organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	ISDP-002, Training Production Process ITTP-015, Website Development-Maintenance P-010, Process Deviation

7.2.3 Customer Communication

The Organization **shall** determine and implement effective arrangements for communicating with Customers in relation to:

Area	Requirement	Response
7.2.3a	Product information,	EOTA Website ITTP-015, Website Development-Maintenance
7.2.3b	Inquiries, contracts or order handling, including amendments, and	EOTA Website ITTP-015, Website Development-Maintenance
7.2.3c	Customer feedback, including Customer complaints.	EOTA Website ITTP-015, Website Development-Maintenance P-005, Student Feedback Process

7.3 Design and Development

7.3.1 Design and Development Planning

The Organization **shall** plan and control the design and development of product.

During the design and development planning, the Organization **shall** determine:

Area	Requirement	Response
7.3.1a	The design and development stages,	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-017, Application Programming
7.3.1b	The review, verification and validation that are appropriate to each design and development stage, and	ISDP-002, Training Production Process ITTP-017, Application Programming
7.3.1c	The responsibilities and authorities for design and development.	ISDP-002, Training Production Process ITTP-017, Application Programming
	The Organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	ISDP-002, Training Production Process ITTP-017, Application Programming
	Planning output shall be updated, as appropriate, as the design and development progresses.	ISDP-002, Training Production Process ITTP-017, Application Programming
	Note: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.	

7.3.2 Design and Development Inputs

Area	Requirement	Response
	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4).	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming P-003, Control of Records

These inputs **shall** include:

Area	Requirement	Response
7.3.2a	Functional and performance requirements,	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming
7.3.2b	Applicable statutory and regulatory requirements,	ISDP-002, Training Production Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming
7.3.2c	Where applicable, information derived from previous similar designs, and	ISDP-002, Training Production Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming
7.3.2d	Other requirements essential for design and development.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming
	The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming

7.3.3 Design and Development Outputs

Area	Requirement	Response
	The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming

Design and development outputs **shall**:

Area	Requirement	Response
7.3.3a	Meet the input requirements for design and development,	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming
7.3.3b	Provide appropriate information for purchasing, production and service provision,	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming
7.3.3c	Contain or reference product acceptance criteria, and	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming
7.3.3d	Specify the characteristics of the product that are essential for its safe and proper use.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming
	Note: Information for production and service provision can include details for the preservation of product.	

7.3.4 Design and Development Review

Area	Requirement	Response
	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1).	ISDP-002, Training Production Process ISDP-014, Course Evaluation and Close Out Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming P-010, Process Deviation
7.3.4a	To evaluate the ability of the results of design and development to meet requirements, and	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming QAMP-002, Course Maintenance Process
7.3.4b	To identify any problems and propose necessary actions.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming QAMP-002, Course Maintenance Process P-010, Process Deviation
	Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming P-003, Control of Records

7.3.5 Design and Development Verification

Area	Requirement	Response
	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ISDP-014, Course Evaluation and Close Out Process ITTP-017, Application Programming P-003, Control of Records

7.3.6 Design and Development Validation

Area	Requirement	Response
	Design and Development Validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ISDP-014, Course Evaluation and Close Out Process ITTP-017, Application Programming P-003, Control of Records

7.3.7 Control of Design and Development Changes

Area	Requirement	Response
	Design and Development Changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming P-003, Control of Records

7.4 Purchasing

7.4.1 Purchasing Process

Area	Requirement	Response
	The Organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the Supplier (vendor) and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.	ADMP-001, Procurement Process ADMP-002, Vendor Selection and Management Process ADMP-003, Receiving Inspection Process P-011, Nonconforming Material/Product Process
	The Organization shall evaluate and select Suppliers (vendors) based on their ability to supply product in accordance with the Organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary action arising from the evaluation shall be maintained (see 4.2.4).	ADMP-001, Procurement Process ADMP-002, Vendor Selection and Management Process P-003, Control of Records

7.4.2 Purchasing Information

Purchasing information **shall** describe the product to be purchased, including where appropriate:

Area	Requirement	Response
7.4.2a	Requirements for approval of product, procedures, processes and equipment,	ADMP-001, Procurement Process
7.4.2b	Requirements for qualification of personnel, and	ADMP-001, Procurement Process
7.4.2c	Quality management system requirements.	ADMP-001, Procurement Process
	The Organization shall ensure the adequacy of specified purchase requirements prior to their communication to the Supplier (vendor).	ADMP-001, Procurement Process

7.4.3 Verification of Purchased Product

Area	Requirement	Response
	The Organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	ADMP-003, Receiving Inspection Process

Area	Requirement	Response
	Where the Organization or its Customer intends to perform verification at the Supplier's (vendor's) premises, the Organization shall state the intended verification arrangements and method of product release in the purchasing information.	ADMP-001, Procurement Process

7.5 Product and Service Provision

7.5.1 Control of Production and Service Provision

The Organization **shall** plan and carry out production and service provision under controlled conditions. Controlled conditions **shall** include, as applicable:

Area	Requirement	Response
7.5.1a	The availability of information that describes the characteristics of the product,	ITTP-015, Website Development-Maintenance ITTP-016, WBT Programming ITTP-017, Application Programming ISDP-016, ILT Course Development Process ISDP-017, Exercise Development Process ISDP-018, WBT Course Development Process
7.5.1b	The availability of work instructions, as necessary,	ITTP-015, Website Development-Maintenance ITTP-016, WBT Programming ITTP-017, Application Programming
7.5.1c	The use of suitable equipment,	ITTP-015, Website Development-Maintenance ITTP-016, WBT Programming ITTP-017, Application Programming
7.5.1d	The availability and use of monitoring and measuring equipment,	N/A
7.5.1e	The implementation of monitoring and measurement, and	P-006, Measurement, Analysis, and Improvement
7.5.1f	The implementation of product release, delivery and post-delivery activities.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-016, WBT Programming ITTP-017, Application Programming

7.5.2 Validation of Processes for Production and Services Provision

Area	Requirement	Response
	The Organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.	N/A
	Validation shall demonstrate the ability of these processes to achieve planned results.	N/A

The Organization **shall** establish arrangements for these processes including, as applicable:

Area	Requirement	Response
7.5.2a	Defined criteria for review and approval of the processes,	N/A
7.5.2b	Approval of equipment and qualification of personnel,	P-003, Control of Records
7.5.2c	Use of specific methods and procedures,	N/A
7.5.2d	Requirements for records (see 4.2.4), and	P-003, Control of Records
7.5.2e	Re-validation.	N/A

7.5.3 Identification and Traceability

Area	Requirement	Response
	Where appropriate, the Organization shall identify the product by suitable means throughout product realization.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-016, WBT Programming ITTP-017, Application Programming ITTP-018, Media Inventory Control P-003, Control of Records
	The Organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.	
	Where traceability is a requirement, the Organization shall control the unique identification of the product and maintain records (see 4.2.4).	

7.5.4 Customer Property

Area	Requirement	Response
	The Organization shall exercise care with Customer property while it is under the Organization’s control or being used by the Organization. The Organization shall identify, verify, protect and safeguard Customer property provided for use or incorporation into the product. If any Customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).	ADMP-003, Receiving Inspection Process MGTP-003, Control of Customer Property MGTP-005, EOTA Inventory Process MGTP-006, EOTA Key Control Process P-003, Control of Records
	Note: Customer property can include intellectual property and personal data.	

7.5.5 Preservation of Product

Area	Requirement	Response
	The Organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.	ISDP-002, Training Production Process ITTP-012, Graphic Design Support ITTP-014, Network Technical Support ITTP-015, Website Development-Maintenance ITTP-018, Media Inventory Control

7.6 Control of Monitoring and Measuring Equipment – **EXCLUDED FROM SCOPE OF REGISTRATION**

8.0 Measurement, Analysis and Improvement

8.1 General

The Organization **shall** plan and implement the monitoring, measurement, analysis and improvement processes needed:

Area	Requirement	Response
8.1a	To demonstrate conformity to product requirements,	P-006, Measurement, Analysis and Improvement
8.1b	To ensure conformity of the quality management system, and	P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-007, Internal Audit P-008, Corrective/Preventive Action
8.1c	To continually improve the effectiveness of the quality management	P-004, Business System Management Review

Area	Requirement	Response
	system.	P-005, Student Feedback Process P-006, Measurement, Analysis and Improvement P-007, Internal Audit P-008, Corrective/Preventive Action P-012, Process/Continual Improvement
	This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	P-006, Measurement, Analysis and Improvement P-004, Business System Management Review

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Area	Requirement	Response
	As one of the measurements of the performance of the quality management system, the Organization shall monitor information relating to customer perception as to whether the Organization has met customer requirements. The methods for obtaining and using this information shall be determined.	ITTP-011, Student Support ISDP-002, Training Production Process P-004, Business System Management Review P-005, Student Feedback Process P-008, Corrective/Preventive Action
	Note: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.	

8.2.2 Internal Audit

The Organization **shall** conduct internal audits at planned intervals to determine whether the quality management system:

Area	Requirement	Response
8.2.2a	Conforms to the planned arrangements (see 7.1) to the requirements of this International Standard and to the quality management system requirements established by the Organization, and	P-004, Business System Management Review P-007, Internal Audit
8.2.2b	Is effectively implemented and maintained.	P-004, Business System Management Review P-007, Internal Audit
	An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the	MGTP-002, Skill Set / Training Process P-007, Internal Audit

Area	Requirement	Response
	results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.	
	A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.	P-007, Internal Audit
	Records of the audits and their results shall be maintained (see 4.2.4).	P-007, Internal Audit P-003, Control of Records
	The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).	P-007, Internal Audit P-004, Business System Management Review P-008, Corrective/Preventive Action

8.2.3 Monitoring and Measurement of Processes

Area	Requirement	Response
	The Organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.	P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-007, Internal Audit P-008, Corrective/Preventive Action P-011, Nonconforming Material/Product Process
	Note: When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.	

8.2.4 Monitoring and Measurement of Product

Area	Requirement	Response
	The Organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming P-006, Measurement, Analysis and Improvement P-003, Control of Records
	Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming P-003, Control of Records P-006, Measurement, Analysis and Improvement
	The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and, where applicable, by the customer.	ISDP-002, Training Production Process ISDP-005, Functional-Job-Task Analysis Process ITTP-015, Website Development-Maintenance ITTP-017, Application Programming P-006, Measurement, Analysis and Improvement

8.3 Control of Nonconforming Product

Area	Requirement	Response
	The Organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.	P-011, Nonconforming Material/Product Process

Where applicable, the Organization **shall** deal with nonconforming product by one or more of the following ways:

Area	Requirement	Response
8.3a	By taking action to eliminate the detected nonconformity;	P-011, Nonconforming Material/Product Process
8.3b	By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;	P-011, Nonconforming Material/Product Process

Area	Requirement	Response
8.3c	By taking action to preclude its original intended use or application;	P-011, Nonconforming Material/Product Process
8.3d	By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.	P-011, Nonconforming Material/Product Process
	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	P-011, Nonconforming Material/Product Process
	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	P-003, Control of Records P-011, Nonconforming Material/Product Process

8.4 Analysis of Data

Area	Requirement	Response
	The Organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.	P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-008, Corrective/Preventive Action QAMP-001, Periodic Reports Process

The analysis of data **shall** provide information relating to:

Area	Requirement	Response
8.4a	Customer satisfaction (see 8.2.1),	ITTP-011, Student Support P-004, Business System Management Review P-005, Student Feedback Process QAMP-001, Periodic Reports Process
8.4b	Conformity to product requirements (see 8.2.4),	P-011, Nonconforming Material/Product Process P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-008, Corrective/Preventive Action QAMP-001, Periodic Reports Process
8.4c	Characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4), and	ITTP-011, Student Support P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-008, Corrective/Preventive Action

Area	Requirement	Response
		QAMP-001, Periodic Reports Process
8.4d	Suppliers (vendors) (see 7.4).	ADMP-002, Vendor Selection and Management Process P-006, Measurement, Analysis and Improvement

8.5 Improvement

8.5.1 Continual Improvement

Area	Requirement	Response
	The Organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	P-004, Business System Management Review P-006, Measurement, Analysis and Improvement P-007, Internal Audit P-008, Corrective/Preventive Action P-012, Process/Continual Improvement Q-002, Quality Policy QAMP-001, Periodic Reports Process

8.5.2 Corrective Action

Area	Requirement	Response
	The Organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.	P-008, Corrective/Preventive Action P-011, Nonconforming Material/Product Process P-012, Process/Continual Improvement

A documented procedure **shall** be established to define requirements for:

Area	Requirement	Response
8.5.2a	Reviewing nonconformities (including customer complaints),	P-004, Business System Management Review P-011, Nonconforming Material/Product Process P-005, Student Feedback Process P-008, Corrective/Preventive Action
8.5.2b	Determining the causes of nonconformities,	P-008, Corrective/Preventive Action
8.5.2c	Evaluating the need for action to ensure that nonconformities do not recur,	P-008, Corrective/Preventive Action P-011, Nonconforming Material/Product Process

Area	Requirement	Response
8.5.2d	Determining and implementing action needed,	P-008, Corrective/Preventive Action
8.5.2e	Records of the results of action taken (see 4.2.4), and	P-008, Corrective/Preventive Action P-003, Control of Records
8.5.2f	Reviewing the effectiveness of the corrective action taken.	P-004, Business System Management Review P-008, Corrective/Preventive Action

8.5.3 Preventive Action

Area	Requirement	Response
	The Organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.	P-008, Corrective/Preventive Action

A documented procedure **shall** be established to define requirements for:

Area	Requirement	Response
8.5.3a	Determining potential nonconformities and their causes,	P-008, Corrective/Preventive Action
8.5.3b	Evaluating the need for action to prevent occurrence of nonconformities,	P-008, Corrective/Preventive Action
8.5.3c	Determining and implementing action needed,	P-008, Corrective/Preventive Action
8.5.3d	Records of results of action taken (see 4.2.4), and	P-003, Control of Records P-008, Corrective/Preventive Action
8.5.3e	Reviewing the effectiveness of the preventive action taken.	P-004, Business System Management Review P-008, Corrective/Preventive Action

ISO 9001:2000 Clause No.	Paragraph/Figure/Table/Note	Amended Text
Annex A	All – Informative – Not Applicable	<i>Updated to reflect ISO 9001:2008 versus ISO 14001:2004</i>
Annex B	All – Informative	<i>Updated to reflect ISO 9001:2008 versus ISO 9001:2008</i>
Bibliography	New and amended references	<i>Updated to reflect new standards (Including ISO 9004, currently under revision), new editions of standards, or withdrawn standards.</i>